



Issue #299

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## Email Edition

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### Immunization Program

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## Decisions of the U.S. Court of Federal Claims in Omnibus Autism Proceeding

Three rulings related to autism and vaccine injury compensation cases were issued on February 12<sup>th</sup> by the Special Masters of the U.S. Court of Federal Claims. The rulings were part of the Omnibus Autism Proceeding created by the National Vaccine Injury Compensation Program to handle the large volume of claims that vaccines induce autism.

In order to ensure that the over 4,900 cases were dealt with in a timely manner, the U.S. Court of Federal Claims divided the claims into three different theories:

**Theory 1:** MMR in combination with thimerosal-containing vaccines can cause autism.

**Theory 2:** Thimerosal-containing vaccines alone can cause autism.

**Theory 3:** The MMR vaccine alone can cause autism. In three separate rulings, each of the Special Masters ruled that the measles-mumps-rubella vaccine, whether administered alone or in conjunction with thimerosal-containing vaccines, were not causal factors in the development of autism or autism spectrum disorders. The specific rulings can be found at: [U.S. Court of Federal Claim's Webpage](#).

### Statement from the Department of Health and Human Services Regarding the Decisions of the U.S. Court of Federal Claims in the Omnibus Autism Proceeding

"As these cases illustrated, there's no doubt that autism and autism spectrum disorders place a heavy burden on many families. That is one reason why the U.S. Department of Health and Human Services (HHS) continues to support research to better understand the cause of autistic disorders and develop more effective methods of treatment.

The medical and scientific communities have carefully and thoroughly reviewed the evidence concerning the vaccine-autism theory and have found no association between vaccines and autism. If parents have questions or concerns about childhood vaccines, they should talk with their child's health care provider.

Hopefully, the determination by the Special Masters will help reassure parents that vaccines do not cause autism.

More information is available from HHS about [autism and autism spectrum disorders](#), and from the Health Resources and Services Administration (HRSA) about [the National Vaccine Injury Compensation Program](#). All HHS press releases, fact sheets and other press materials are available at the [HHS Newsroom](#).

## Hib Availability (As of February 27, 2009)

Vaccine Presentation	March Doses Allocated	Doses Available to Order
ActHIB®	6,580	6,580
PedvaxHIB®	200	200
Pentacel®	8,840	8,840

The state has used its entire allotment of ActHib® and PedvaxHib® for February. Our March allotment will begin on March 1. Pentacel® is the only Hib containing presentation that may be available in quantities greater than those allocated. Please order as usual and we will ship what we can as the vaccines become available.

## Vaccine Spotlight: Gardasil®

Gardasil® is a quadrivalent Human Papillomavirus (HPV) vaccine manufactured by Merck. It was licensed for use in 2006 for use among females 9-26 years of age and is currently the only licensed vaccine for HPV in the United States.

**Recommended Schedule** The recommended age for routine vaccination in the United States is 11-12 years. The vaccine can be given as young as 9 years of age at the discretion of the clinician. Gardasil® is administered in a three-dose series administered by intramuscular injection.

Dose Number	Recommended age	Minimum Age	Recommended Interval	Minimum Interval
HPV-1	11-12 years	9 years	2 months	4 weeks
HPV-2	11-12 years (+2 months)	109 months	4 months	12 weeks
HPV-3	11-12 years (+6 months)	114 months	—	—

Doses administered at an interval shorter than the minimum interval should not be counted as valid and should be repeated. There is a minimum of 24 weeks required between Dose 1 and Dose 3. If the HPV vaccine schedule is interrupted, the vaccine series does not need to be restarted. The duration of protection from HPV vaccine is not known. Studies to investigate this issue are in progress. Booster doses are not recommended at this time.

Gardasil® is not approved for use among females younger than 9 years or older than 26 years of age. Use of the vaccine in females younger than 9 years or older than 26 years is not recommended. Studies with females older than 26 years of age are ongoing. Gardasil® is not licensed for use among males. Off-label use among males is not recommended. While data on immunogenicity and safety are available for 9-15 year-old males, there are no data on efficacy in males at any age. Efficacy studies among males are under way.

**Administration** Intramuscular (IM) injection, Given in deltoid of the arm (Choose the injection site and needle length appropriate to the person's age and body mass)

- Can be given at the same visit as other vaccines, separate injection sites by 1-2 inches
- Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. After thorough agitation Gardasil® is a white, cloudy liquid.
- Do not dilute or mix with other vaccines

**Adverse Reactions** Local reactions at the site of injection most common adverse reaction reported in clinical trials, with no serious adverse reactions have been reported. A variety of systemic adverse reactions were reported by vaccine recipients, including nausea, dizziness, myalgia and malaise. Clinicians should consider observing persons for 15–20 minutes after vaccination.

**Vaccine Safety** In February of 2009, news reports of a 16 year old girl in Kansas who was diagnosed with Cerebral Vasculitis by a local neurologist caused by "post Gardasil® complications." Neither the girl's primary care provider or neurologist were identified in the story. National media coverage of this report may increase parental concerns regarding the safety of Gardasil®.

As of April 30, 2008, VAERS received 7,802 reports after Gardasil® vaccination in the U.S. The number of serious adverse events reported to VAERS following HPV vaccine is less than 7% of the total number of reports received. In comparison, the overall average in VAERS for any serious adverse event ranges from 10%-15%; thus, the percentage of serious reports for Gardasil® is less than the overall average. Information on Gardasil® vaccine reports to VAERS can be found on the Immunization Safety Office's web page at [www.cdc.gov/vaccinesafety/vaers/gardasil.htm](http://www.cdc.gov/vaccinesafety/vaers/gardasil.htm).

**Storage & Handling** Gardasil® is supplied as single-dose (0.5mL) vials and prefilled syringes

- Must be kept at refrigerator temperature (35°-46°F; 2°-8°C) at all times
- Gardasil® must be protected from light
- Gardasil® must never be frozen. Vaccine exposed to freezing temperature must not be used
- Gardasil® contains no thimerosal or antibiotics

**CHIRP Users** Enter as HPV

**VFC Availability** Gardasil® is available to order through the VFC program. If you do not see Gardasil® on your order form, please contact us at (800) 701-0704 for an updated form. For more information regarding and VFC eligibility, please contact the ISDH Immunization program at (800) 701-0704 or [immunize@isdh.in.gov](mailto:immunize@isdh.in.gov).

## Questions of the Week

If the first 3 doses of DTaP and Hib are given as TriHIBit®, do they count as valid?

TriHIBit® is licensed only for the 4th dose in the DTaP/Hib series. If a child received TriHIBit® for one or more of the first three doses of the series, the DTaP doses can be counted as valid as long as the minimum age and minimum intervals were observed. The Hib doses are *not* valid, and you should revaccinate the child with single antigen Hib vaccine or Pentacel® (if single antigen hib is not available) as appropriate for the child's age. Refer to the catch-up schedule.

Trihibit should only be given after age 12 months, and the child should have had at least one prior dose of Hib. It is not that children receive no protection from the Hib component of TriHIBit® if they receive it as doses 1-3, but the response is less than that of single-antigen Hib vaccine. To be licensed, FDA requires that the components of a combination vaccine perform as well or better than their single-antigen counterparts. CDC recommends that if you know a child received TriHIBit® as part of the primary series, the Hib doses should be repeated.

Adapted From:  
<http://www.cdc.gov/vaccines/svpd-vac/combo-vaccines/DTaP-Td-DT-faqs-nipinfo-DTaP-DT-Td.htm>

## Upcoming Events

March 5, 2009

8:30am - 1:00pm (EST)

### Immunizations from A to Z PLUS

Methodist Hospital, South Pavilion Auditorium, 600 Grant St, Gary, IN  
For more information, contact Jodi Morgan (317) 650-5051 or [jmorgan@isdh.in.gov](mailto:jmorgan@isdh.in.gov)

[Click here for registration form.](#)

March 11, 2009

8:30am - 3:30pm (EST)

### Immunizations from A to Z PLUS

Greenfield Fire Station #2, 210 W. New Road, Greenfield, IN 46140  
For more information, contact Jill King (317) 501-7461 or [jiking@isdh.in.gov](mailto:jiking@isdh.in.gov)

[Click here for registration form.](#)

March 17, 2009

8:30am - 1:00pm (EST)

### Immunizations from A to Z PLUS

County City Building, 227 W Jefferson Blvd, 8<sup>th</sup> Floor Board Room, South Bend, IN  
For more information, contact Jodi Morgan (317) 650-5051 or [jmorgan@isdh.in.gov](mailto:jmorgan@isdh.in.gov)

[Click here for registration form.](#)

March 19, 2009

12:00pm - 3:00pm (EST)

### IIC Meeting

Rice Auditorium, ISDH

March 20, 2009

9:30am - 11:30am

### CHIRP User Group Meeting

St. Vincent Clay Hospital Medical Office Building, Community Room, 1214 East National Ave, Brazil, IN

March 20, 2009

1:30pm - 3:00pm

### Introduction to CHIRP Training

St. Vincent Clay Hospital, Medical Office Building, Community Room, 1214 East National Ave, Brazil, IN

March 27, 2009

8:30am - 3:00pm (EST)

### Immunizations from A to Z PLUS

Spring Mill State Park, Oak Room SR 60 East, Mitchell, IN  
For more information, contact Sharon Griffin at (317) 670-8826 or [sgriffin@isdh.in.gov](mailto:sgriffin@isdh.in.gov)

[Click here for registration form.](#)

## Immunization Schedule Basics

The Advisory Committee on Immunization Practices (ACIP) annually reviews the recommended Immunization Schedules. Updated revisions, reflecting current recommendations for licensed vaccines, are printed each January for the Childhood and Adolescent Schedules and usually in October for the Adult Schedule. Physicians and other medical providers should always refer to the latest schedules which are available from the Centers for Disease Control and Prevention (CDC) website at <http://www.cdc.gov/vaccines/>.

### Routine Immunization Schedules

Childhood Schedule:	Birth through 6 years of age
Adolescent Schedule:	7 through 18 years of age
Adult Schedule:	≥ 19 years of age
Catch-up Schedule:	4 months through 18 years of age

### Clarifying the Schedule

#### *Childhood, Adolescent, and Adult Immunization Schedules*

The Childhood, Adolescent, and Adult Schedules are formatted in the same fashion with recommended ages listed horizontally along the top and the vaccines vertically to the left. Shaded bars indicate the range of acceptable ages for administering each vaccine dose.

**Yellow Bar** For persons who meet the recommended age requirement but lack evidence of immunity, i.e., lack documentation of immunity or have no evidence of prior infection.

**Purple Bar** Vaccine not recommended for all persons but for those with increased risk for certain diseases.

**Blue Bar (Adolescent Schedule)** The blue bar indicates catch-up vaccination that is needed; however, it is still important to refer to the Catch-up Schedule.

**Red Bar (Adult Schedule)** Unique to the Adult Schedule are the red bars indicating when a condition is contraindicated, i.e. MMR & varicella are contraindicated in pregnant women.

**White Bar (Adult Schedule)** A legend box has been added to the Adult Schedule to clarify the meaning of blank spaces in the table. It is used to indicate no recommendation.

Footnotes are listed at the bottom of each vaccine schedule to clarify recommendations.

Adult Schedule - a separate chart is included at the bottom of this schedule for vaccines that might be indicated for adults based on medical & other conditions.

### *Catch-up Immunization Schedule*

Used to accelerate the schedule for children 4 months through 18 years of age who start late or are at least one month behind

Uses minimum intervals between doses

Keep in mind a vaccine series does not need to be restarted, or doses added, regardless of the time that has elapsed between doses

### Tips for Healthcare Staff

- Post the *latest* schedule(s) in exam and medication rooms and at the scheduling desk.
- Carry laminated pocket copies of the schedule available at <http://www.cdc.gov/vaccines/recs/schedules/pocketsize.htm>
- Do not try to memorize the schedule. Refer to the *correct* schedule for age appropriate vaccines that are due.
- Always read the footnotes as they contain important information and are frequently revised with the schedule.
- Report adverse events to VAERS at <http://www.vers.hhs.gov> or by telephone, 800-822-7967.

The recommended immunization schedules for persons aged 0 through 18 years and the catch-up immunization schedule have been approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

The Recommended Adult Immunization Schedule has been approved by the Advisory Committee on Immunization Practices, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the American College of Physicians.

## VFC & Medicaid

The Indiana Health Coverage Programs (IHCP) is committed to ensuring that the nearly 850,000 Hoosiers covered by Medicaid have continuous and easy access to quality healthcare.

Medicaid and the Vaccines for Children (VFC) program are closely tied together. Medicaid eligible children are automatically eligible for VFC vaccine.

**The VFC administration fee cannot be billed to the member since the vaccine and administration fee are reimbursed by Medicaid.**

Additional information can be found at [www.indianamedicaid.com/ihcp/publications/maxfee/fee\\_schedule.asp](http://www.indianamedicaid.com/ihcp/publications/maxfee/fee_schedule.asp).

If you are currently not enrolled as a Medicaid provider, and would like more information on how to become a Medicaid provider, please contact an Electronic Data Systems (EDS) provider field consultant at (317) 488-5154.

## Individual Cases of Varicella (Chickenpox) Now Reportable

As of December 12, 2008, all primary cases of varicella (chickenpox) are reportable to the local health department under 410 IAC 1-2.3-47. Healthcare providers should report all individual cases of chickenpox to the local health department within 72 hours for investigation by department staff.

Cases of varicella should be reported to the local health department using the Report of Confidential Communicable Diseases Form available at <http://www.in.gov/isdh/files/43823.pdf>.

The complete revised Communicable Disease Control Rule is available at <http://www.in.gov/legislative/iac/T04100/A00010.PDF>.

## Save the Date!

### 2009 Public Health Nurse Conference

**May 28, 2009; 1pm to 4pm (Optional workshops and open forum)**

**May 29, 2009; 9am to 4pm**

**IUPUI Campus Center, Indianapolis, IN**

*Sessions include:*

- Keynote by Dr. Judy Monroe on Public Health Workforce and Accreditation
- ISDH/LHD PHN orientation
- SharePoint training
- Integrating Preparedness into Public Health
- Understanding the new Communicable Disease Rule
- Injury Prevention

Registration is Free, but pre-registration will be required.

For more information, contact Jessica Trimble at (317) 234-6623 or [jtrimble@isdh.in.gov](mailto:jtrimble@isdh.in.gov).

## Adult Immunization Schedules Available

Adult Immunizations Schedules, (11x17, full color, on cardstock), are currently available. Please contact Alex ThurdeKoos at [althurdekoos@isdh.in.gov](mailto:althurdekoos@isdh.in.gov) if you would like to receive an Adult Schedule.

## Vaccine Availability

DTaP Infanrix® (GSK) is temporarily unavailable in both 10 pack, single dose vial and 5 pack, single dose syringes. GSK expects to ship replenishment orders to McKesson Distribution Centers in early to mid March 2009.

Daptacel® (sanofi pastuer) 10 pack, single dose vial and Tripedia® (sanofi pastuer) 10 pack, single dose vial are available to order.

Td Decavac® (sanofi pastuer) has been unavailable for many months due to issues related to product dating. Product is expected to arrive at McKesson Distribution Centers in early March 2009.

## Get Ready for National Infant Immunization Week

*National Immunization Week (NIIW)* will be celebrated April 25-May 2, 2009 in conjunction with *Vaccination Week in the Americas (VWA)*. The theme for NIIW is "Love them. Protect them. Immunize Them." Visit [the NIIW Events Webpage](#) for planning and evaluation resources, public relations materials, and communication campaign materials.

## Immunization Program Leadership Changes

The ISDH Immunization program has experienced leadership changes. Former program director, Amanda Mizell, departed the program in early February 2009. We would like to thank Amanda for her service to the Immunization Program and wish her all the best with her future career.

Dr. Joan Duwe, Medical Director and Dawn Adams, Operations Manager both of the Public Health and Preparedness Commission will be sharing the duties of Interim Immunization Program Director until the position is filled.

## McKesson Packing Boxes

Remember to save a small supply of McKesson boxes for vaccine returns. Return labels are supplied with the boxes.